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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,977	07/14/2003	Brian L. Bates	PA-5335-RFB	5904

9896 7590 11/19/2007

COOK GROUP PATENT OFFICE
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EXAMINER	
SWEET, THOMAS	
ART UNIT	**PAPER NUMBER**
3774	

MAIL DATE	DELIVERY MODE
11/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/618,977	BATES ET AL.	
	Examiner	Art Unit	
	Thomas J. Sweet	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/28/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, see page 10 of the remarks, filed 08/28/2007, with respect to the rejection under 35 USC 112 have been fully considered and are persuasive. The rejection of claim 47 has been withdrawn.

Applicant's arguments with respect to claims 35-48 have been considered but are moot in view of the new ground(s) of rejection.

It is now admitted prior art formerly rejected as well known in the art of balloon catheters to use a polyamide, polypropylene, polyether block amide and polyethylene for the balloon membrane since the official notice was not addresses in the response.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56 (not material to examination as defined in 37 CFR 1.56(a))

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 35-40, 42, 45, 49-50 and 52-53 are rejected under 35 U.S.C. 102(a and e) as being anticipated by Palasis et al (US 6369039). Palasis et al discloses a method (balloon angioplasty, fig 4) of delivering a lipophilic bioactive material (col 5, lines 1-47, i.e. paclitaxel, line 22) to an interior wall of a body vessel from an implantable medical device (angioplasty balloon, col 3, line 35) having an expandable balloon with the lipophilic bioactive material (paclitaxel) on an outer surface of the balloon (col 3, lines 16-17 as the coating per se, i.e. no other material and by fluid delivery to the surface of the balloon), the method comprising the steps of: inserting the balloon into a body vessel (fig. 4), the balloon being free of : a coating atop the bioactive material, a time-release layer, a containment material and a containment layer (the agent is the coating per se or the fluid drug);

advancing the balloon within the body vessel to a treatment site within the body vessel (fig. 4);

inflating the balloon at the treatment site to contact the bioactive material with an inner wall of the body vessel (col 6, lines 42-43);

maintaining the bioactive material on the outer surface of the inflated balloon in contact with the inner wall of the body vessel while the balloon is inflated (col 6, line 46-50, about 1 minute);

deflating the balloon after contacting the bioactive material with the inner wall of the body vessel; and removing the deflated balloon from the body vessel (the balloon inherently needs to be deflated to be removed, col 6, lines 50-51).

With regard to claim 38, wherein the bioactive material further comprises a diagnostic agent (col 8, lines 22-23).

With regard to claims 39 and 40, angioplasty is on the coronary artery (col 6,line 39).

With regard to claim 51,the balloon is attached to a catheter shaft that includes a guide wire lumen (guide wire is disclosed in the examples) and an inflation lumen for inflating the balloon (the use of a guide wire and balloon with the catheter inherently require lumens for use).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 43 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Palasis et al. Palasis et al discloses a method as discussed above. However, Palasis et al remains silent as to the material of the balloon catheter, specifically a polyamide, polypropylene, polyether block amide or polyethylene. It is admitted prior art to use a polyamide, polypropylene, polyether block amide and polyethylene for a balloon membrane in the art of balloon catheters. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize polyamide, polypropylene, polyether block amide or polyethylene as the balloon catheter member either inherently or as mere substitution of one functionally equivalent balloon material for another within the art of balloon catheters.

Claims 41, 44, 46-48 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palasis et al in view of Barry et al. (US 2003/0059454/provisional 60/324095). Palasis et al discloses a method as discussed above. However, Palasis et al remains silent as to any dosing levels including about 5-500 micrograms. Barry et al teaches another method of delivering a lipophilic bioactive material (paclitaxel) to an interior wall of a body vessel from an implantable medical device (fig. 1) in the range of about 5 to about 500 micrograms (50-345) for the purpose preventing restenosis in a compatible range. The remainder of the range is obvious, since this can be determined by experimentation. It would have been obvious to one of ordinary skill in the art at the time the invention was made to dose the paclitaxel coating of Yang et al in the range of about 5 to about 500 micrograms in order to compatibly prevent restenosis.

With regard to claim 48, Yang et al remains silent as to any dosing levels including a total of about 0.2 to about 20 micrograms of paclitaxel or a paclitaxel derivative per mm2 of the outer surface of the expandable balloon. Barry et al teaches from about 0.2 to about 20 micrograms (.6-4, fig. 1). As before the remained of the range is obvious, since this can be determined by experimentation. As modified above the claim is met.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 08/28/2007 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 6:45am - 5:15pm, Tu-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thomas J Sweet
Examiner AU 3774